RotaTeq Found Effective at Expiration Date

BY ALICIA AULT
Contributing Writer

WASHINGTON — Merck’s experimental RotaTeq vaccine was effective against moderate and severe rotavirus at the end of its shelf life, which appears to be 18 months, lead investigator Umesh Parashar, M.D., reported at the National Immunization Conference sponsored by the Centers for Disease Control and Prevention.

A new vaccine is eagerly anticipated, because rotavirus causes 440,000 deaths and leads to 2.1 million inpatient visits in children under age 5 worldwide each year, said Dr. Parashar of the National Center for Infectious Diseases at the Centers for Disease Control and Prevention (CDC). Rotavirus causes 5% of deaths in children under age 5 worldwide. In the United States, there are few deaths—only 20-60 per year—but there are 200,000-272,000 emergency department visits and 400,000 outpatient visits because of rotavirus annually.

Stan Block, M.D., a pediatrician in private practice in Bardstown, Ky., presented the RotaTeq data on behalf of trial sites in the United States and Finland.

RotaTeq is a pentavalent oral vaccine, aiming to provide protection against the G1, G2, G3, G4, and P1 strains. From 2002 to 2004, 1,310 healthy infants aged 6-12 weeks were assigned to receive three doses of RotaTeq (at the end of shelf life) or placebo. The doses were given 4-10 weeks apart. Children with a gastrointestinal disorder, recent surgery, or acute fever or who had taken steroids within 2 weeks of the trial were excluded. RotaTeq could be given simultaneously with other vaccines, said Dr. Block.

Children were monitored for acute gastroenteritis through one rotavirus season.

There were 69 cases of rotavirus, for an overall efficacy of 72.5%. For severe acute gastroenteritis, the vaccine was 100% effective, and for both moderate and severe gastroenteritis, it was 76.3% effective.

The vaccine also appeared to be very safe. There were five potential cases of intussusception (all were in the placebo group), but all were negatively adjudicated by an independent safety monitoring board, Dr. Block said.

Children who received RotaTeq did have a statistically significant increase in temperature after the first dose, compared with placebo—13.4% of RotaTeq vaccinees, compared with 8.8% of placebo recipients. However, there was no increase in rates of fever after the second or third dose, he said. Only one child was documented to have a rotavirus vaccine strain a few days after the first dose of vaccine. Merck is continuing a larger, multiple-dose vaccine safety study. Preliminary results were presented at the CDC’s Advisory Committee on Immunization Practices meeting in February, said Penny Heaton, director of clinical research at Merck.

So far, there have been 12 cases of intussusception in the RotaTeq group and 15 in the placebo group, she said.